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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,504	03/23/2001	Michael Castro	2658	5642

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EXAMINER

STEWART, ALVIN J

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 12/12/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/815,504

Applicant(s)

CASTRO ET AL.

Examiner

Alvin J Stewart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29,31-33,35,36 and 41-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29,31-33,35,36 and 41-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 April 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION***Information Disclosure Statement***

The information disclosure statement filed July 25, 2003 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or *other information* (the applicant should file the form PTO 1449) submitted for consideration by the Office. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-29, 35, 36 and 41-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Schönhöffer US Patent 5,571,192.

Schönhöffer discloses a fusion implant comprising an implant member (2), the implant member (2) has a first end, a second end, and an outer wall (3) defining an internal cavity (see fig. 3). The outer wall has a plurality of grooves (the valleys of the threaded surface have been interpreted as the plurality of the grooves, see attachment to determine the location of the grooves), which encircle the whole circumference of the outer wall, and segments the implant member into a plurality of ring-like segments (see attachment). Each ring-like segment includes a plurality of apertures (9 & 10) extending in communication with the internal cavity. The first and second ends of the implant member are in mechanical connection to a plurality of caps (1 & 1').

Regarding claim 23, the grooves are capable of acting as a cutting guide. For example, the outer thread of the tubular member (2) of the Schönhöffer is capable of creating a threaded bore into the walls of the vertebrae.

Regarding claim 24, the grooves are capable of acting as a measurement guide. For example, by measuring the separation between one groove and the collar (6) and/or the thickened center region (8) the surgeon is capable of determining an exact length.

Regarding claim 26, see the notes made by the Examiner in the attachment determining the different lengths in the segments.

Regarding claim 27, see Figure 2.

Regarding claim 29, the end cap has a face (15) having at least one aperture (see Figure 11).

Regarding claim 36, the Examiner interpreted the plurality of locking pins as the plurality of peaks created by the threaded bore in each cap (see Fig. 1).

Regarding claim 41, the prior art discloses an implant that can be set in any vertebra disk space at any acceptable length range. The length of the implant is increased by rotating the center element (2) in order to force out the end elements and bring their outer ends at a certain length. The length, of course, will depend on the natural length of the natural disk that is going to be replaced. Therefore, the Examiner has interpreted lines 14-16 broadly. If the surgeon knows the total length of the ablated natural disk and the initial length of the artificial implant then the surgeon by looking at the grooves is capable of determining (before implantation) the desire length of the implant when the center element is rotated. Therefore, the surgeon can

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measure the length of the disk space by placing physically the implant in the expanded state before is implanted.

Note: The claims disclosed above are given their broadest reasonable interpretation, especially claim 41, lines 14-16. In re Pearson, 181 USPQ 641 (CCPA 1974).

Regarding claim 42, see col. 2, lines 9-12.

Regarding new claim 44, the Examiner interpreted the phrase "at least one planar groove" as following:

- The broader meaning of the word "planar" in the Merriam-Webster Dictionary is ---of or pertaining to a geometric plane; flat or level. The meaning of the word "flat" is ---having a surface without projections or depressions---. Therefore, the incline threaded surface of the Schönhöffer groove is planar because the surface of each groove does not have projections or depressions.

Regarding claim 45, if the Examiner draw an imaginary line crossing the valley of the threaded surface of Figure 2 (see attachment) then the above line will be perpendicular to the end of the implant member (see attachment).

Regarding claim 46, lines 11-12, it is *clearly shown* in Fig. 2 (see attachment) that the grooves closed to the ends do not intersect the apertures (additionally, some other grooves along the length of the implant are capable of not intersecting the apertures).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schönhöffer US Patent 5,571,192 in view of Schönhöffer US Patent 6,015,436.

Schönhöffer ('192) discloses the invention substantially as claimed. However, Schönhöffer does not disclose a plurality of spikes arranged radially about the face of the end caps.

Schönhöffer teaches an implantable disk prosthesis comprising an implant member (1) having a first end and a second end having a plurality of spikes (12) radially (see Figure 3) about the face of the first and second ends for the purpose of having a good attachment with the walls of the vertebrae (see col. 4, lines 13-24).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the distal ends of the Schönhöffer reference ('192) with the distal ends spikes of the Schönhöffer reference ('436) in order to have a good attachment with the walls of the vertebrae.

Response to Arguments

Applicant's arguments with respect to claims 21-29, 31-33, 35, 36, and 41-46 have been considered but they are not persuasive.

The Applicant traverse the Examiner's rejections by disclosing that the Schönhöffer reference only shows a threaded surface and the threaded surface creates grooves which cannot segment the implant member into discreet ring-like segments. The Applicant's representative has not provided sufficient claims limitations in order to differentiate the Applicants' invention of the Schönhöffer invention. The Applicants' representative is only disclosing at least one

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groove that encircles the outer wall of the implant (the groove not necessarily has to encircle the whole circumference of the outer wall and they do not have to have a particular shape) and that the groove makes the discrete ring-like segments. For the above reasons, the Examiner is positively sure that the grooves shown in the Schönhöffer reference clearly read on the grooves of this application.

Regarding claim 36, the Examiner traverses the Applicants' remarks and agrees with his previous claim interpretation. The peaks of the grooves of each cap end have been interpreted as the locking pins that engage the first or second end of the implant. Nowhere in claim 36 discloses the action of snapping the end caps into the implant body. For the above reasons the Examiner believe that the rejection is proper.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J Stewart whose telephone number is 703-305-0277. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-308-2708 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.


Alvin Stewart

December 5, 2003.


CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

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Attachment

